

CLAIMS

*Sub A1* 5  
1. A preparation for determining pyrimidine metabolizing activity, comprising as an active ingredient a pyrimidine compound or its metabolite in which at least one of C, O and N is labeled with an isotope.

10 2. A preparation according to claim 1, wherein the pyrimidine compound or its metabolite is a substrate for a pyrimidine metabolizing enzyme or a precursor of the substrate.

*Sub A2* 15 3. A preparation according to claim 2, wherein the pyrimidine metabolizing enzyme is at least one member selected from the group consisting of dihydropyrimidine dehydrogenase, dihydropyrimidinase and  $\beta$ -ureidopropionase.

20 4. A preparation according to any one of claims 1 to 3, wherein the pyrimidine compound or its metabolite is at least one member selected from the group consisting of 5-fluorouracil, uracil, thymine, 5-fluorodihydrouracil, dihydrouracil, dihydrothymine, fluoro- $\beta$ -ureidopropionic acid,  $\beta$ -ureidopropionic acid,  $\beta$ -ureidoisobutyric acid, doxifluridine, tegafur and carmofur.

25 5. A preparation according to any one of claims 1 to 4, wherein the pyrimidine compound or its metabolite is a compound in which at least one of C and O is labeled with an isotope, and wherein the pyrimidine compound or its metabolite is capable of producing isotope-labeled  $\text{CO}_2$

in vivo after administration.

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K3*

6. A preparation according to any one of claims 1 to 5, wherein the isotope is at least one member selected from the group consisting of  $^{13}\text{C}$ ,  $^{14}\text{C}$ ,  $^{18}\text{O}$  and  $^{15}\text{N}$ .

5 7. A method for determining pyrimidine metabolizing activity in an individual subject, comprising administering a preparation according to any one of claims 1 to 6 to the subject, and measuring behavior of an isotope-labeled metabolite.

10 8. A method for determining pyrimidine metabolizing activity in an individual subject, comprising administering a preparation according to any one of claims 1 to 6 to the subject, and measuring excretion behavior of an isotope-labeled metabolite excreted from the body.

15 9. A method for determining pyrimidine metabolizing activity in an individual subject, comprising administering a preparation according to any one of claims 1 to 6 to the subject, and measuring behavior of isotope-labeled  $\text{CO}_2$  excreted in the expired air.

20 10. A method according to claim 7 or 8, wherein the pyrimidine metabolizing activity to be determined is an activity of at least one pyrimidine metabolizing enzyme selected from the group consisting of dihydropyrimidine dehydrogenase, dihydropyrimidinase and  $\beta$ -ureidopropionase.

25 11. A method for assessing pyrimidine metabolizing activity in an individual subject, comprising

administering a preparation according to any one of claims 1 to 6 to the subject, and measuring behavior of an isotope-labeled metabolite, and comparing the behavior in the subject with behavior in a healthy subject.

5        12. A method for assessing pyrimidine metabolizing activity in an individual subject, comprising administering a preparation according to any one of claims 1 to 6 to the subject, measuring excretion behavior of an isotope-labeled metabolite excreted from the body, and

10      comparing the excretion behavior in the subject with excretion behavior in a healthy subject.

13. A method for assessing pyrimidine metabolizing activity in an individual subject, comprising administering a preparation according to any one of claims 1 to 6 to the subject, measuring excretion behavior of isotope-labeled CO<sub>2</sub> excreted in the expired air, and comparing the CO<sub>2</sub> excretion behavior in the subject with CO<sub>2</sub> excretion behavior in a healthy subject.

14. A method for establishing a dosage regimen of a pyrimidine drug for an individual subject, comprising assessing pyrimidine metabolizing activity in the subject by the method according to claim 10 or 11 before administration of the drug, and determining the dosage regimen based on the pyrimidine metabolizing activity.

25      15. A method according to claim 14, wherein the pyrimidine drug is a fluorouracil drug selected from the

group consisting of 5-fluorouracil, tegafur, carmofur and doxifluridine.

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